

Notice of Allowability

Application No.

09/831,901

Examiner

Isis Ghali

Applicant(s)

TAKADA, KANJI

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 01/20/06.
2. ☒ The allowed claim(s) is/are 1-8,10-18,20,21 and 23-25.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The drawings filed 05/25/01 require correction as indicated by attached "Notice of Draftsperson's Patent Drawing Review" (PTO-948). Corrected drawing sheet(s) must be submitted including the changes. I.G. 4/17/06

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 04/17/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Isis Ghali

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TC 1600

4/17/06

The receipt is acknowledged of applicants' amendment and remarks filed January 20, 2006.

Claims 1-8, 10-18 and 20-25 are pending.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Arnold Turk on April 17, 2006.

The application has been amended as follows:

- In claim 1, line 10, delete the phrase "may attach" between the word "layer" and the word "to" and insert the phrase --- is attached ---.
- Cancel claim 22.

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance: none of US '478 and US '105 teach the three-layered oral formulation that comprises a layer to be attached to the mucosa and made of enteric polymer, a drug containing-layer, and a

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protective layer structured and arranged for preventing digestive juice from permeating into the drug carrying layer. In addition, none of the cited references teach that the enteric polymer layer (adhesion site-controlling layer) and the protective layer are attached to protect the drug-containing layer. US '478 teaches the outer layer slows the release of drug till this layer dissolves or disperses, while the presently claimed protective layer is structured and configured to protect the drug carrying layer. In addition, US '478 disclosed two embodiments that have three layers, however, the first embodiment that is described by Figure 2 and at col.16, lines 51-60, has an adhesive layer that is not enteric polymers and its outer layer is not protective because it dissolves and is not attached to the adhesive layer. The second embodiment is described in figure 9 and col.22, lines 4-20, and has a water-soluble layer located between an adhesive layer and a drug-containing layer, thus having no protective function. With regard to US '105, the reference teaches a substrate layer, which the examiner interpreted as protective layer, is coated with the active agent containing layer which is coated by the enteric polymer, i.e. the substrate is not a protective layer because it is in the middle and not attached to the outer layer. Thus, the claims as amended are not anticipated or obvious over any of US '478 or US '105.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Claims 1-8, 10-18, 20, 21, 23-25 are allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595.

The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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4/17/06